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52

APPLICATION NO.	FILING DATE	FIRST NAMED INVENTOR	ATTORNEY DOCKET NO.	CONFIRMATION NO.
10/733,063	12/11/2003	Christoph Widmer	32784US5	7834
116	7590	10/05/2005	EXAMINER	
PEARNE & GORDON LLP 1801 EAST 9TH STREET SUITE 1200 CLEVELAND, OH 44114-3108			WARREN, DAVID S	
			ART UNIT	PAPER NUMBER
			2837	

DATE MAILED: 10/05/2005

Please find below and/or attached an Office communication concerning this application or proceeding.

Office Action Summary

Application No.

10/733,063

Applicant(s)

WIDMER, CHRISTOPH

Examiner

David S. Warren

Art Unit

2837

-- The MAILING DATE of this communication appears on the cover sheet with the correspondence address --

Period for Reply

A SHORTENED STATUTORY PERIOD FOR REPLY IS SET TO EXPIRE 3 MONTH(S) OR THIRTY (30) DAYS, WHICHEVER IS LONGER, FROM THE MAILING DATE OF THIS COMMUNICATION.

- Extensions of time may be available under the provisions of 37 CFR 1.136(a). In no event, however, may a reply be timely filed after SIX (6) MONTHS from the mailing date of this communication.
- If NO period for reply is specified above, the maximum statutory period will apply and will expire SIX (6) MONTHS from the mailing date of this communication.
- Failure to reply within the set or extended period for reply will, by statute, cause the application to become ABANDONED (35 U.S.C. § 133). Any reply received by the Office later than three months after the mailing date of this communication, even if timely filed, may reduce any earned patent term adjustment. See 37 CFR 1.704(b).

Status

- 1) ☒ Responsive to communication(s) filed on 22 July 2005.
- 2a) ☐ This action is **FINAL**. 2b) ☐ This action is non-final.
- 3) ☐ Since this application is in condition for allowance except for formal matters, prosecution as to the merits is closed in accordance with the practice under *Ex parte Quayle*, 1935 C.D. 11, 453 O.G. 213.

Disposition of Claims

- 4) ☒ Claim(s) 1,3-21 and 23-28 is/are pending in the application.
- 4a) Of the above claim(s) _____ is/are withdrawn from consideration.
- 5) ☐ Claim(s) _____ is/are allowed.
- 6) ☒ Claim(s) 1,3-21 and 23-28 is/are rejected.
- 7) ☐ Claim(s) _____ is/are objected to.
- 8) ☐ Claim(s) _____ are subject to restriction and/or election requirement.

Application Papers

- 9) ☐ The specification is objected to by the Examiner.
- 10) ☒ The drawing(s) filed on 11 December 2003 is/are: a) ☒ accepted or b) ☐ objected to by the Examiner.
Applicant may not request that any objection to the drawing(s) be held in abeyance. See 37 CFR 1.85(a).
Replacement drawing sheet(s) including the correction is required if the drawing(s) is objected to. See 37 CFR 1.121(d).
- 11) ☐ The oath or declaration is objected to by the Examiner. Note the attached Office Action or form PTO-152.

Priority under 35 U.S.C. § 119

- 12) ☐ Acknowledgment is made of a claim for foreign priority under 35 U.S.C. § 119(a)-(d) or (f).
- a) ☐ All b) ☐ Some * c) ☐ None of:
1. ☐ Certified copies of the priority documents have been received.
 2. ☐ Certified copies of the priority documents have been received in Application No. _____.
 3. ☐ Copies of the certified copies of the priority documents have been received in this National Stage application from the International Bureau (PCT Rule 17.2(a)).

* See the attached detailed Office action for a list of the certified copies not received.

Attachment(s)

- | | |
|--|---|
| 1) <input checked="" type="checkbox"/> Notice of References Cited (PTO-892) | 4) <input type="checkbox"/> Interview Summary (PTO-413)
Paper No(s)/Mail Date. _____ |
| 2) <input type="checkbox"/> Notice of Draftsperson's Patent Drawing Review (PTO-948) | 5) <input type="checkbox"/> Notice of Informal Patent Application (PTO-152) |
| 3) <input checked="" type="checkbox"/> Information Disclosure Statement(s) (PTO-1449 or PTO/SB/08)
Paper No(s)/Mail Date <u>7/22/05</u> . | 6) <input type="checkbox"/> Other: _____ |

DETAILED ACTION

Claim Rejections - 35 USC § 103

1. The following is a quotation of 35 U.S.C. 103(a) which forms the basis for all obviousness rejections set forth in this Office action:

(a) A patent may not be obtained though the invention is not identically disclosed or described as set forth in section 102 of this title, if the differences between the subject matter sought to be patented and the prior art are such that the subject matter as a whole would have been obvious at the time the invention was made to a person having ordinary skill in the art to which said subject matter pertains. Patentability shall not be negated by the manner in which the invention was made.

2. Claims 1, 3, 4, 17 – 20, 23, 24, 27, and 28 are rejected under 35 U.S.C. 103(a) as being unpatentable over Moro et al. (5,045,266) in view of Stanton (5,185,802).

Regarding independent claims 1 and 20, Moro discloses the use of hearing device (col. 1, lines 62 – 64) and a substance provided on the surface of the hearing device (col. 3, lines 14 – 19). The Examiner maintains that *re*lease of a substance will place the substance at the surface of the hearing aid shell. Regarding claims 2 and 22, Moro discloses the hearing aid electronics fit within a cavity within the earmold, thus making the earmold a “shell.” Furthermore, for the substance to be released, it must be within the shell. (For the purposes of this rejection, shell and earmold are deemed synonymous). Regarding claims 3 and 23, Moro states that the substance is controllably released (col. 3, lines 16 – 19). Regarding claims 4, 17, 18 and 24, Moro discloses the use of germicides, fungicides, antibiotics, analgesics, etc. All are deemed functionally equivalent to being “antibiotically active” or “an antimicrobial agent.”

Regarding claim 19, migration of the medically active ingredients to the surface of the

Art Unit: 2837

Moro hearing device shell, will provide the functional equivalent of a "film." Regarding new claims 27 and 28, it is inconceivable that the substance and component would be applied with the device within the individual's ear. Certainly one of ordinary skill would think to apply the substance to the shell before being inserted in the ear. Likewise for the component, while it may be possible to add the component with the hearing device within the ear, one of ordinary skill would find it much easier (i.e., obvious) to remove the device from the ear before exchanging the component. Moro does not disclose the use of a hearing device having an outer shell and another component, wherein the shell is adapted to a shape of an application area and wherein the shell can be exchanged from the other member remote from the individual. Stanton discloses the use of a shell (12) and removable (i.e., *exchangeable*) another component (14; fig. 2). Stanton teaches to remove and "immediately replace" the component (col. 1, lines 25 – 29), in other words, to exchange the component. It would have been obvious to one of ordinary skill in the art to combine the teachings of Moro with those of Stanton to obtain a hearing aid shell adapted to a surface of an individual for applying a substance and having an exchangeable component. The motivation for making this combination is to provide a means to maintain hygienic contact with an individual's skin over a prolonged period of time – as would be necessary with any hearing aid device.

3. Claims 5 – 16, 21, 25, and 26, are rejected under 35 U.S.C. 103(a) as being unpatentable over Moro et al. and Stanton (both discussed supra) and in view of

Art Unit: 2837

Zaffaroni (3,996,934). The teachings of Moro and Stanton have been discussed supra. Regarding claims 5, 11 and 12, Moro and Stanton do not disclose the use of a rough surface. Zaffaroni discloses the use of a porous surface, wherein any porous surface will have a degree of roughness (col. 4, lines 51 – 57). The Examiner notes that the porous structure of Zaffaroni applies to both a covering membrane and the matrix (which is impregnated with the medically active ingredient). Regarding claims 6, 8, and 10, both Moro and Zaffaroni disclose placing material within the matrix (or shell) – as defined by Applicant, this will constitute a film. Regarding claim 7, the Examiner maintains that all substances have structure, e.g., molecular structure, polymeric structure, etc. Regarding claim 9, Zaffaroni discloses matrix dimensions of 50 angstroms (or less) to 100 microns, a matrix of 50 angstroms will deliver a substance of 50 angstroms or less, certainly 50 angstroms can be fairly interpreted as a “micro-structure.” Regarding claim 13, (“slow” is a relative term) both Moro and Zaffaroni disclose slow release (e.g., see Zaffaroni, col. 12, last sentence). Regarding claims 14 – 16, Zaffaroni does not specifically disclose the use of a liquid, gel, and/or paste, but instead states “the viscosity” (col. 4, lines 57 – 64) may be chosen in accordance with the matrix pore size. The Examiner maintains that this is functionally equivalent to using structures, micro-structures, with a liquid, gel, and/or paste. In other words, the viscosity (i.e., liquid, gel, or paste) may be varied in accordance with pore size to achieve a desired active ingredient release rate – which is vital in administering medicaments. The limitations of claim 21 are discussed supra with regard to claims 5 – 9. Regarding new claims 25 and 26, as stated supra, it is inconceivable that the

Art Unit: 2837

substance and component would be applied with the hearing device within the individual's ear. Certainly one of ordinary skill would think to apply the substance to the shell before being inserting the device in the ear. Likewise for the component, while it may be possible to exchange the component with the hearing device within the ear, one of ordinary skill would find it much easier (i.e., obvious) to remove the device from the ear before exchanging the component. It would have been obvious to one of ordinary skill in the art to combine the teachings of Moro and Stanton with those of Zaffaroni to obtain a hearing device with a substance applied thereto, wherein the shell provides a matrix for the substance. The motivation for making this combination is improved transdermal drug delivery.

Response to Arguments

4. Applicant's arguments with respect to claims 1 – 4, 17 – 20, 22 – 24, 27, and 28 have been considered but are moot in view of the new ground(s) of rejection.

Regarding claims 5 – 16, 21, 25, and 26, the Applicant argues that the Examiner's motivation to combine the references "merely states an advantage of the **invention**, not a teaching in the references that would motivate one to make the combination resulting in the invention." The Examiner maintains that the use of the Zaffaroni teachings within the device as taught by Moro and Stanton, would render the Moro and Stanton invention with "improved transdermal drug delivery." The Examiner maintains the motivation.

Conclusion

5. **THIS ACTION IS MADE FINAL.** Applicant is reminded of the extension of time policy as set forth in 37 CFR 1.136(a).

A shortened statutory period for reply to this final action is set to expire **THREE MONTHS** from the mailing date of this action. In the event a first reply is filed within **TWO MONTHS** of the mailing date of this final action and the advisory action is not mailed until after the end of the **THREE-MONTH** shortened statutory period, then the shortened statutory period will expire on the date the advisory action is mailed, and any extension fee pursuant to 37 CFR 1.136(a) will be calculated from the mailing date of the advisory action. In no event, however, will the statutory period for reply expire later than **SIX MONTHS** from the mailing date of this final action.

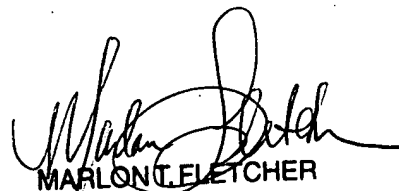
Any inquiry concerning this communication or earlier communications from the examiner should be directed to David S. Warren whose telephone number is 571-272-2076. The examiner can normally be reached on M-F, 9:30 A.M. to 6:30 P.M..

If attempts to reach the examiner by telephone are unsuccessful, the examiner's supervisor, David Martin can be reached on 571-272-2800 ext 37. The fax phone number for the organization where this application or proceeding is assigned is 571-273-8300.

Art Unit: 2837

Information regarding the status of an application may be obtained from the Patent Application Information Retrieval (PAIR) system. Status information for published applications may be obtained from either Private PAIR or Public PAIR. Status information for unpublished applications is available through Private PAIR only. For more information about the PAIR system, see <http://pair-direct.uspto.gov>. Should you have questions on access to the Private PAIR system, contact the Electronic Business Center (EBC) at 866-217-9197 (toll-free).

dsw



MARLON T. FLETCHER
PRIMARY EXAMINER